February 8, 2002

BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

Vanguard Medical Concepts, Inc. (Vanguard)[1] respectfully submits this petition under Section 515 of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 10.30. The purpose of this petition is twofold. First, Vanguard respectfully requests that the Commissioner of Food and Drugs (the Commissioner) modify the February 14, 2002, deadline for Food and Drug Administration (FDA) clearance of premarket notification submissions (510(k)s) for Class II reprocessed devices, as required by the August 14, 2000, "Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Guidance). Vanguard respectfully requests that this deadline be modified to extend until August 14, 2002. Second, Vanguard respectfully requests that the Commissioner modify the February 14, 2002[2], deadline for approval of premarket approval applications (PMAs) for Class III reprocessed devices, as required by the Guidance. Vanguard respectfully requests that the PMA deadline be modified to extend until August 14, 2004. Vanguard further requests that August 14, 2004 be the submission deadline for PMAs, rather than the approval deadline and that the agency permit continued marketing during FDA review of the completed PMA.

Due to the urgency of this petition, Vanguard will assume it to be denied if FDA has not replied by February 14, 2002.

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[1] Vanguard is a third-party reprocessor of medical devices labeled for single use, headquartered in Lakeland, Florida.

[2] The Guidance originally stipulated an August 14, 2001 PMA approval deadline. This deadline was subsequently extended to February 14, 2002. See U.S. Food and Drug Administration Talk Paper, TO1-37, FDA Actions on Reprocessed Single Use Devices, August 16, 2001, *available at www.fda.gov/bbs/topics/ANSWERS/2001/ANS01098.html.*

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A. Actions Requested

1. Vanguard requests that FDA modify the February 14, 2002, deadline for agency clearance of 510(k)s for Class II reprocessed devices. Vanguard requests that this deadline be extended until August 14, 2002.

2. Vanguard requests that FDA modify the February 14, 2002, PMA approval deadline for Class III reprocessed devices. Vanguard requests that the timeframe be modified to allow submission of a PMA until August 14, 2004. Vanguard further requests that FDA allow continued marketing during agency review of the completed PMA.

B. Statement of Grounds

1. FDA's February 14, 2002, 510(k) clearance deadline is unreasonably short and should be lengthened.

As a threshold matter, Vanguard observes that FDA gave the reprocessing industry a mere 12 months in which to prepare 510(k) submissions for a multitude of products. Vanguard worked diligently and spent hundreds of thousands of dollars to meet this unreasonable deadline – and, ultimately, Vanguard succeeded. On or before the August 14, 2001 deadline, Vanguard submitted numerous 510(k) submissions. Having accomplished this nearly impossible task, Vanguard is now faced with the disturbing reality that it still may be forced off the market because FDA is unable to meet its February 14, 2002 clearance deadline.

Vanguard strongly objects to the notion that its ability to market should be dependent upon FDA clearing its 510(k) submissions within a pre-determined timeframe. Indeed, this approach departs dramatically from prior agency practice. Rather, the agency historically has imposed premarket submission deadlines, and has permitted marketing for as long as it takes for FDA to complete its review.[3]

It clearly was unrealistic to expect that FDA would complete its review of all reprocessed device 510(k)s within six months. Because of agency resource constraints, delays in reviewing and responding to 510(k)s and PMAs are common, and, given that FDA reviewers have no experience

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[3] As one example, in 1994, when FDA determined that software products used by blood establishments to manage donor information were subject to regulation as medical devices, the agency initially provided an entire year for manufacturers to submit PMAs or 510(k)s, and the agency subsequently extended the submission deadline for another year. See 59 Fed. Reg. 44, 991 (Aug. 31, 1994); 60 Fed. Reg. 51, 802 (Oct. 3, 1995). The manufacturers were then permitted to stay on the market during FDA review of the submissions.

with submissions for reprocessed devices, delay was inevitable. Moreover, in a number of cases, the agency has "changed its mind" midstream regarding what Vanguard must include in its submissions. In addition, FDA has been very slow in issuing important guidance concerning 510(k) and PMA submission requirements. As one example, the agency did not provide labeling guidance relevant to 510(k) and PMA submissions until July 30, 2001 – only two weeks before the 510(k) submission deadline. These agency delays and vacillations have further slowed the 510(k) review process – and they further highlight the unfairness of holding Vanguard, and the entire reprocessing industry, hostage to an arbitrary agency clearance deadline.

If there were evidence that protection of the public health warranted requiring such a compressed timeframe, Vanguard would support FDA's February 14, 2002 deadline. However, the facts clearly show that no such public health concern exists. Indeed, FDA itself acknowledges that it has "been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[4]

In fact, Vanguard is concerned that the public health may well be harmed if FDA maintains the February 14, 2002 deadline. Reprocessing allows hospitals to achieve significant cost savings, while maintaining the highest standards of patient care. As Dr. Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the Mayo Clinic, wrote in a June 23, 1999 letter to Senator Paul Wellstone (D-MN):

> For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures . . . . Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.[5]

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[4] See attached Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to the Medical Device Manufacturers Association (October 6, 1999) (Attachment A).

[5] See Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota to Senator Paul Wellstone (June 23, 1999).

The bottom line is that the reprocessed devices in question are being safely used by the nation's top hospitals. They will not suddenly become "unsafe" on February 15, and the reprocessing industry should not be forced to incur devastating economic loss because FDA has been unable to meet an arbitrary 510(k) clearance deadline.

2. FDA's February 14, 2002, PMA deadline is unreasonably short and should be lengthened.

Requiring a company to submit and obtain FDA approval of a PMA within 18 months provides insufficient time to: 1) develop the basic requirements for a PMA; 2) develop and conduct the necessary non-clinical tests; 3) develop the clinical protocol; 4) identify and enroll clinical sites and investigators; 5) obtain Institutional Review Board (IRB) approval; 6) locate, enroll, and obtain informed consent from suitable subjects; 7) conduct the clinical study; 8) conduct the necessary patient follow-up; 9) obtain and analyze the results of the clinical study; and 10) draft, revise, finalize, and submit the PMA. This is especially true in this case, given that the companies required to submit the PMA have never been so required in the past. The submission of a PMA was a brand new requirement for the devices in question – reprocessed ablation catheters – which have been safely reprocessed for over a decade.

The established timeframe is dramatically shorter than the timeframes that historically have been permitted for similarly situated entities. Indeed, there are numerous instances where once FDA determined that a PMA or 510(k) was necessary for a "type" of device currently on the market, the agency allowed companies up to several years to make the submission. Furthermore, as noted above, in these instances, as well as in similar instances related to drug approvals, none of the manufacturers was held hostage to FDA approving the product in a pre-determined timeframe. For example when Congress enacted the Medical Device Amendments of 1976, manufacturers of pre-amendment Class III devices were allowed a minimum of 30 months to submit a PMA. 21 U.S.C. § 351(f)(2). Manufacturers were then permitted to stay on the market for as long as it took for FDA to approve or deny the PMA.

As stated above, Vanguard would support the February 14 deadline if there were evidence that it would inure to the benefit of public health. However, the evidence is clearly to the contrary. As Johns Hopkins Hospital observed, access to reprocessed ablation catheters helps physicians provide better care to patients:

> An additional benefit of this interaction is the improved patient care from a level of comfort provided the physician who can use a variety of catheter designs and shapes without incurring the guilty feeling that he/she has dramatically increased the cost to the patient.[6]

Confronted with an impossibly short amount of time for submitting and receiving PMA approval, Vanguard will be forced off the market – as will the other third-party reprocessors of ablation catheters who have not gained FDA approval.[7] The draconian timeframes required under the Guidance have already forced hospitals to cease reprocessing devices that require PMAs. Therefore, beginning August 15, these important devices will no longer be available to U.S. hospitals.

3. Conclusion.

The approach laid out in the Guidance is unprecedented. Proponents of additional regulatory burdens for reprocessors argued that original equipment manufacturers and reprocessors should have a "level playing field." By providing reprocessors such a limited time to prepare, submit, and receive FDA approvals and clearances, FDA has created a "playing field" where no reprocessor has a fair shot at "winning." When reprocessing loses, patients and hospitals lose too. Vanguard has worked in good faith to meet the Guidance requirements, though Vanguard suspected on August 14, 2000 that strict adherence to these timeframes would be impossible.

Objections to the timeframes through its trade association, the Association of Medical Device Reprocessors (AMDR), and in numerous meetings and phone calls with the agency, have proven fruitless.[8] This Citizen Petition now asks FDA to modify the February 14, 2002, 510(k) clearance deadline to extend until August 14, 2002. This Citizen Petition also asks FDA to extend the time permitted for submission of a PMA until August 14, 2004, and to permit continued marketing during agency review of the completed PMA.

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[6] See attached letter from Johns Hopkins Hospital (Attachment B); see also Comments to Docket No. 00D-0053 regarding FDA's draft guidance documents, submitted by the Association of Medical Device Reprocessors (April 11, 2000) (Attachment C).

[7] It is Vanguard's understanding that no other reprocessors will have attained PMA approval by February 14.

[8] For a more detailed review of these issues, see AMDR Comments (Attachment C).

C. Environmental Impact

This petition is entitled to a categorical exclusion under 21 C.F.R. § 25.30 and § 25.31.

D. Economic Report

Vanguard will submit an economic analysis upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petitioner relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Chuck Masek CPP

Chuck Masek
Chief Executive Officer and President
Vanguard Medical Concepts Inc.

CM:la
Enclosures
cc: Dr. David Feigal
Phil Philips
Larry Spears